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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,179	06/20/2000	Maura Rooney	BSP2102US02	5883

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/597,179

Applicant(s)

ROONEY ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 25, 26, 28-30, 32-39 and 57-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 25, 26, 28-30, 32-39 and 57-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 22, 30, 34, 57, 64 and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,833,631 to Nguyen.

In regards to claims 22, 30, 34, 57, 64 and 68, Nguyen discloses a guide wire (Figure 2) including an elongate core (102) composed of a nickel-titanium alloy (Col. 5, lines 6 – 8), a proximal portion and a distal portion; a continuous unitary coil (204) composed of a second material (Col. 3, lines 56 – 67; Col. 4, lines 45 – 48) and that surrounds a substantial portion of the length of the core and extending distal of the core (Col. 4, lines 36 – 44); and a polymeric tip (206) extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material (202; Col. 3, lines 32 - 34). The distal portion of the core is tapered. The coil comprises a coating (Col. 4, lines 6 – 7). The core as disclosed by Nguyen includes a constant diameter length.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 22, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,622,184 to Ashby et al. in view of U.S. Patent No. 5,924,998 to Cornelius et al.

In regards to claims 22, 28 and 30, Ashby et al. discloses a guide wire including an elongate core (16) having a length, a proximal portion (18), and a distal portion (21); a continuous, unitary coil (30) composed of stainless steel (Col. 4, lines 23 – 26) surrounding a substantial portion of the length of the core and extending distal of the distal portion of the core (Col. 5, lines 15 – 19); and a polymeric tip (85; Col. 6, lines 54 – 57) extending from a distal portion of the coil. The tip (85) is connected to the core by a polymeric material (Col. 4, lines 63 – 67; Col. 6, lines 21 – 24). The distal portion of the core is tapered (Figure 4). Ashby et al. discloses the core being composed of stainless steel as well as other materials (Col. 4, lines 15 – 18). Ashby et al. fails to disclose the core being formed of a nickel-titanium alloy. However, Cornelius et al. discloses a guide wire wherein the core is composed of either stainless steel or a nickel-titanium alloy (Col. 3, lines 27 – 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Ashby et al. to be composed of a nickel-titanium alloy as taught by Cornelius et al. in that Cornelius et al. discloses stainless steel and nickel-titanium alloy to be equivalent and therefore interchangeable.

5. Claims 22, 25, 26, 28, 30, 33 – 35, 38, 39, 57 – 60, 63 – 65, 68 – 74, 76, 78, 79, 82 – 85 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,139,640 to Rost et al. in view of U.S. Patent No. 5,833,631 to Nguyen.

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6. In regards to claims 22, 25, 26, 28, 30, 33 – 35, 38, 39, 57 – 60, 63 – 65, 68 – 74, 76, 78, 79, 82 – 85 and 87, Rost et al. discloses a guide wire including an elongate core (60) composed of a nickel-titanium alloy (Col. 9, lines 5 - 16) including a length having a constant diameter, a proximal and distal portion and a continuous, unitary coil (62) composed of a second material and that surrounds the length of the core and extends distal of the distal portion of the core. The second material comprises stainless steel (Col. 9, lines 5 – 16). A distal portion of the core is tapered (70). Rost et al. discloses the coil having a pitch that varies at least once (Col. 6, lines 46 – 47), having a circular cross-section and alternatively being formed of a cross-wound multifilar wire (Col. 6, lines 55 – 60). The coil comprises a first coil portion (35) having a first pitch and a second coil portion (37) surrounding the distal portion of the core having a second pitch. Rost et al. discloses the coil comprising a lubricious coating (Col. 9, lines 17 – 24). Rost et al. discloses a polymeric distal tip (40; Col. 6, lines 50 – 54). However, Rost et al. fails to disclose the polymeric tip being connected to the core by a polymeric material. Nguyen discloses a guide wire (Figure 2) including an elongate core (102) composed of a nickel-titanium alloy (Col. 5, lines 6 – 8), a proximal portion and a distal portion; a continuous unitary coil (204) composed of a second material (Col. 3, lines 56 – 67; Col. 4, lines 45 – 48) and that surrounds a substantial portion of the length of the core and extending distal of the core (Col. 4, lines 36 – 44); and a polymeric tip (206) extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material (202; Col. 3, lines 32 - 34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guide wire as disclosed by Rost et al. to include a polymeric material connecting the tip to the core as taught by Nguyen in order to allow the tip of the guide wire to be shapeable using, e.g. steam or hot air; leading to much less trauma (Col. 2, lines 31 – 36).

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7. Claims 29, 61 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,139,640 to Rost et al. in view of U.S. Patent No. 5,833,631 to Nguyen as applied to claims 22, 57 and 70 above, and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claims 29, 61 and 75, Rost et al. in view of Nguyen fails to disclose using a precipitation hardened alloy as the coil material. Beisel discloses a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Rost et al. in view of Nguyen to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

8. Claims 32, 62, 77 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,139,640 to Rost et al. in view of U.S. Patent No. 5,833,631 to Nguyen as applied to claims 22, 57, 70 and 84 above, and further in view of U.S. Patent No. 5,885,227 to Finlayson.

In regards to claims 32, 62, 77 and 86, Rost et al. in view of Nguyen discloses a polymeric tip (114), but fails to disclose the tip including radio-opaque material. Finlayson discloses a guide wire having a polymeric tip (20) that includes radio-opaque material (Col. 3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Rost et al. in view of Nguyen to include radio-opaque material as taught by Finlayson to allow the tip of the guide wire to be seen with an imaging device while performing a medical procedure.

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9. Claims 36, 66, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,139,640 to Rost et al. in view of U.S. Patent No. 5,833,631 to Nguyen as applied to claims 34, 64 and 78 above, and further in view of U.S. Patent No. 5,997,517 to Whitbourne.

In regards to claims 36, 66 and 80, Rost et al. in view of Nguyen discloses a polymeric coating, but fails to disclose the coating being colored. Whitbourne teaches the use of a colored coating with various medical devices such as guide wires to enhance the performance of the devices (Col. 4, lines 2 – 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guide wire as disclosed by Rost et al. in view of Nguyen to include a colored coating as taught by Whitbourne to enhance the performance of the guide wire by assisting in the identification.

10. Claims 37, 67, 81 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,139,640 to Rost et al. in view of U.S. Patent No. 5,833,631 to Nguyen as applied to claims 22, 57, 70 and 84 above, and further in view of U.S. Patent No. 6,245,030 to DuBois et al.

In regards to claims 37, 67, 81 and 88, Rost et al. in view of Nguyen discloses a coil, but fails to disclose the coil comprising a rectangular cross-section. DuBois et al. discloses a guide wire having a coil (14) with a rectangular cross-section (Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Rost et al. in view of Nguyen to include a rectangular cross-section as taught by DuBois et al. in order to provide the clinician with a smoother surface (Col.5, lines 15 – 19).

Response to Arguments

11. Applicant's arguments filed 9/3/04 have been fully considered but they are not persuasive. Applicant has argued that Ashby et al. in view of Cornelius et al. fails to disclose "a polymeric tip extending from a distal portion of the coil". Applicant states that the polymeric tip (85) does not

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even contact the coil (30). However, the claim does not require the tip to be in contact with the coil.

The polymeric tip (85) as disclosed by Ashby et al. does in fact extend away from the coil.


Additionally the tip (85) is connected to the core by a polymeric material (Col. 4, lines 63 – 67; Col. 6, lines 21 – 24).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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